27-0104-1401

STATEMENT

PhRMA
RESEARCH · PROGRESS · HOPE

Statement Regarding the Idaho Board Pharmacy Rule (BOP) Rule with Respect to the Substitution of Interchangeable Biologics

January 19, 2015

Position: Pharmaceutical Research and Manufacturers of America (PhRMA) supports Idaho with respect to the substitution of interchangeable biologics but encourages the legislature to support doctor notification, an important patient protection.

PhRMA supports the BOP rule with respect to the substitution of interchangeable biologics. This rule will allow for the substitution of biologics deemed interchangeable by the Food and Drug Administration (FDA). Importantly, PhRMA encourages the requirement for pharmacists to notify the prescriber if a biosimilars substitution is made.

PhRMA represents innovative biopharmaceutical research and discovery companies devoted to advancing public policies in the U.S. and around the world that support innovative medical research, yield progress for patients today and provide hope for the treatments and cures of tomorrow. PhRMA companies spent an estimated $51 billion in 2013 to discover and develop new medicines.

Understanding the distinction between a chemically synthesized prescription drug and a biologic is important when crafting state law to address pharmacy substitution practices. Unlike traditional medicines, which are chemically synthesized, biologic medicines are more complex and are manufactured from living organisms. A biosimilar product is highly similar to, but not the same as, its FDA-licensed reference biological medicine. Recent federal legislative and regulatory activity has created an abbreviated regulatory pathway for approving biosimilar products. Ensuring patient safety is essential in the implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) and the amendment of state substitution laws to permit the substitution of interchangeable biosimilars.

As written, the rule requires that because biosimilars will not be exactly the same as the reference biologic product, substitution should only occur when the FDA has designated a biologic product as interchangeable with the reference product. PhRMA appreciates the addition of several important patient protections, including:

- The prescriber should be able to prevent substitution. This ensures the prescribing practitioner, who is knowledgeable about a patient's specific health history and therapeutic regimen, has ultimate decision-making authority for patient care.
- The patient, or the patient's authorized representative, should, at a minimum, be notified of the substitution. Patients who are managing chronic conditions often have tried many

27-0101-1401

CSRO
COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

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January 16, 2015

Idaho House of Representatives
State Capitol Building
Health and Welfare Committee
P.O. Box 83720
Boise, Idaho 83702-9103

RE: Proposed Board of Pharmacy Biosimilars Rules 27-0101-1401

Dear Members of the Idaho House Health and Welfare Committee,

On behalf of the Coalition of State Rheumatology Organizations (CSRO), we respectfully request the Idaho House Health Committee reject the Board of Pharmacy Biosimilar Rules, unless it is amended to include post-dispensing prescriber notification.

CSRO is a national organization composed of 30 state and regional professional rheumatology societies formed in order to advocate for excellence in rheumatologic care and to ensure access to the highest quality care for patients with rheumatologic and musculoskeletal disease. Rheumatologists are entrusted with the safe care of patients with rheumatoid arthritis and other autoimmune diseases that require the careful choice of safe and effective pharmaceutical and biological therapies.

Rheumatologists are keenly aware of the dramatic long-term, life-changing clinical improvements that biological agents have on some of the most crippling and disabling conditions that affect Americans. These biologic response modifying agents are available for the treatment of rheumatoid arthritis and other autoimmune diseases and have a significant impact on improving our patients' quality of life, preventing disability, decreasing morbidity and lowering mortality.

In testimony before the Food and Drug Administration (FDA), Dr. Gregory Schimizzi, CSRO Treasurer, noted that there is not sufficient scientific understanding of biosimilars at this time to allow for an interchangeable biological product. As such, Dr. Schimizzi urged FDA to foreclose the interchangeability option until the science advances in this area because anything short of barring interchangeability would be detrimental to patient safety and would erode physician confidence in prescribing these medications.

Assuming that FDA does proceed with finding interchangeability for certain biosimilars, however, the current automatic substitution process used for generic medications in many states is inappropriate for biosimilars. As Dr. Schimizzi explained in his testimony, "The physician should always be involved in decisions regarding selection of the biological product a patient receives. Automatic retail substitution of biotech medicines is not appropriate. Currently, all State laws allow the pharmacist to substitute a less expensive generic product for the brand name product, and the determination of the ability to substitute such products is based on the nonproprietary name. In some states, like Pennsylvania, unless the prescriber signs or initials "brand necessary" or "brand medically necessary," the pharmacist is required by law to provide the generic form, unless the patient demands a brand name drug."

This approach cannot be applied to biosimilars, which are inherently far more complex products than generic drugs. No two patients are the same; in fact, sometimes two individuals who seem to have identical medical conditions "on paper"

27-0101-1407

January 17, 2015

Representative Fred Wood, Chair
Idaho House Health & Welfare Committee
700 West Jefferson Street
Boise, Idaho 83720

Subject: Oppose changes to 27.01.01.– Rules of the Idaho State Board of Pharmacy regarding biosimilar substitution

Dear Chairman Wood:

On behalf of the more than 13,500 members of the American Academy of Dermatology Association ("Academy"), I write in opposition to the changes proposed by the Idaho State Board of Pharmacy regarding biosimilar substitution. In accordance with the proposal, pharmacists would be authorized to substitute biosimilars for biologic drugs without notification to the health care provider. While we applaud the cost benefits that might occur from biosimilars, substituting a biosimilar absent the medical judgment of the patient's prescribing physician could be detrimental to patient safety. According to the Academy's *Position Statement on Generic Therapeutic and Biosimilar Substitution*, such communication should occur by the time of dispensing (see attached).

Dermatologists who treat severe psoriasis call the advent of biologic therapies a revolution. U.S. patents for these therapies expire in the next ten years, which will open the pathway for biosimilars. Manufacturing a biosimilar is much more complex than manufacturing generics for small molecule drugs. Because biologics are manufactured in living organisms, biosimilars are not exact replications of their reference biologic products. Due to this variability, a patient's response to a biosimilar may not always mirror the response to the reference drug. Even minor changes in the manufacturing process can significantly affect the efficacy of the biosimilar. For these reasons, patient substitution decisions for biosimilars should be carefully considered and should include a physician's medical judgment.

A proposal that does not require physician notification of the substitution at the time of dispensing could jeopardize patient safety and it implies that the risks associated with biosimilars are minimal. Further, the concern that notification would impede a patient's access to medication is not justified as most biologics are delivered via shipping to patients through specialty pharmacies as opposed to traditional medications that are purchased at a patient's local pharmacy.

In order to protect Idaho's patients, the Academy strongly opposes the current proposal that would eliminate the physician's role and medical judgment from patient care. The medical community would welcome an opportunity to work with

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27-0101-1401

Re: BoP Biosimilar rule. Please table the rule until amended to include post-dispensing communication between pharmacists and prescribing physicians when biopharmaceutical products are replaced by biosimilar products.

Honorable Idaho Health and Welfare Committee members,

The Idaho Society of Clinical Oncology (ISCO) is comprised of 257 oncology physicians, mid-level healthcare providers, oncology nurses and practice administrators located throughout Idaho. ISCO was established to respond to the legislative and fiscal challenges of our member jurisdiction and to promote improved healthcare services to the community by sharing resources, information and common goals such as patient safety and affordable quality care.

ISCO physicians have been made aware of a proposed rule that is currently being considered that will allow pharmacists to substitute complex specialty medications, known as biologics, with biosimilar drugs without providing any notice or communication to the doctor.

Unlike conventional chemical drugs, biopharmaceutical products typically require the use of living biological host cells for their production. This includes the use of genetic engineering techniques for cloning of the appropriate genetic sequence into a plasmid or viral messenger system, followed by the creation of a host cell expression mechanism and scaling it up for large-scale protein production. The desired protein must then be isolated and purified from the cell culture medium, using purification techniques that maintain the protein's structural and functional integrity. The purified product must then be correctly formulated to ensure that it retains its biological activity up to patient delivery.

The large size and complexity of biopharmaceutical products mean that manufacturing is equally complex, and quality-control processes are vital because the expression of the same genetic construct in different host cell expression systems has a great impact on the final structure of the protein. Patient responses can depend on how a biologic is made. They are highly sensitive to their manufacturing and handling conditions, making them more difficult to create than common chemical drugs. Even something as simple as the altitude of a manufacturing facility can lead to changes in cell behavior and differences in the structure, stability or other quality aspects of the end product. Any of these differences have the potential to affect the treatment's safety, efficacy and/or shelf life, and to increase the risk of an unwanted immune response.

A new class of medications called "biosimilars" will be entering the marketplace in the near future and are touted to be therapeutically equivalent or interchangeable with biologics and are predicted to have a lower cost. However, unlike generic drugs that are identical copies of the original product, biosimilars, as the name implies, are similar but not identical to the pioneer biologic therapy. That slight difference can have huge implications for efficacy and patient safety.

ISCO's concern is that biosimilar manufacturers do not have access to the originator's molecular clone and original cell bank, nor to the exact fermentation and purification process, nor to the active drug substance. They do have access to the commercialized innovator product. Differences in impurities and/or breakdown products can have serious health implications.

ISCO strongly recommends enforcing communication between the pharmacist, patient and oncologist when a biopharmaceutical product is replaced by a biosimilar product. There are ethical considerations and liability issues created when arbitrarily switching drugs used in the treatment of major or life-threatening conditions without informed consent of the patient or the primary caregiver's knowledge.

- Patient Safety - Biosimilars have the potential to create a different response within a patient's body than the original biologic product.

- Informed consent - An informed consent can be said to have been given based upon a clear appreciation and understanding of the facts, implications, and consequences of an action. This cannot be achieved if the pharmacist has switched drugs without the physician's knowledge.

- Physician liability - In cases where a patient is provided insufficient information to make an informed decision, serious ethical and liability issues arise. This is especially imperative when dealing with life-threatening diseases.

- Disjointed care - By personally and furtively switching cancer-fighting agents, pharmacists are removing the oncologist, the person primarily responsible for the treatment of the cancer patient, from the clinical therapeutic decision-making process.

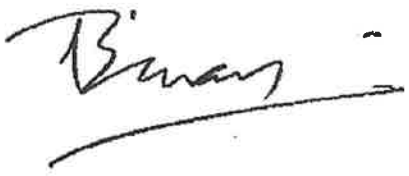
- Monitor adverse events – Healthcare providers require complete and accurate medical records to refer to when treating patients, allowing them to track medications and make informed decisions regarding adverse events. Doctor notification is a simple measure that helps track whether patients are having adverse reactions to biopharmaceutical products vs. newly-introduced biosimilars.

- Efficacy - Oncologists cannot determine the efficacy of biosimilars if they do not know who is receiving them.

The end goal is to make sure that we have a workable system, and that patient safety is of the highest order. If we do not have a clear-cut ability to track individual products once they are marketed, it will be virtually impossible to get at the root cause of any problems that arise.

ISCO strongly recommends enforcing communication between pharmacists and primary care givers when biopharmaceutical products are replaced by biosimilar products.

Sincerely,



Binay Shah, M.D.
President, Idaho Society of Clinical Oncology
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27-0101-1401

AMERICAN COLLEGE OF RHEUMATOLOGY
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January 16, 2015

Idaho House of Representatives
State Capitol Building
Health and Welfare Committee
P.O. Box 83720
Boise, Idaho 83702-9103
(Via electronic delivery)

RE: Letter of comment for Proposed Board of Pharmacy Biosimilar Rules 27-0101-1401

Dear Members of House Health and Welfare Committee:

On behalf of the American College of Rheumatology, **I would again like to express our concern regarding the proposed rules related to the prescription of biological products and interchangeable biological products**. We believe a critical aspect of this issue is the timely notification of changes in patient therapies, which helps to ensure patient safety. In the absence of a requirement to notify in advance of dispensation, notification as early as possible will help to ensure that if there is an adverse event or potentially dangerous immune response, the provider is aware of what has changed. Because of this important consideration, **we respectfully ask that the rules be amended to include prior notification or at a minimum require notification within three days of the prescription being filled.**

Like with innovative biologic products, predicting how a patient will respond to a biosimilar or interchangeable biologic may be challenging. Safety is a critical concern with any of these products that directly impact the immune response in a patient. It is possible that small variations from the original biologic may result in an immune response or other potentially serious side effect, which could result in emergency room visits or hospitalizations. It is very encouraging that Idaho has an opportunity to have guidelines in place to ensure patient safety through appropriate provider engagement and notification, and we applaud you and your colleagues.

The ACR appreciates the opportunity to provide these comments. We are committed to advancing excellence in the care of patients with arthritis and rheumatic and musculoskeletal diseases, which includes serious conditions such as rheumatoid arthritis and other debilitating and potentially-disabling rheumatic diseases. If we may assist you with any additional information or questions, please contact Starla Tanner at stanner@rheumatology.org or by telephone at (404) 633-3777.

Thank you very much for the work you do and for your consideration of this request.

Sincerely,

E. William St.Clair, MD
President, American College of Rheumatology

27-0101-1401

Legislative Services Office
Idaho State Legislature

Eric Milstead
Director

Serving Idaho's Citizen Legislature

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Legislative Research Analyst - Elizabeth Bowen

DATE: September 30, 2014

SUBJECT: Board of Pharmacy

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1401)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy (Fee Rule) - Temporary and Proposed Rule (Docket No. 27-0101-1402)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1403)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1404)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1405)

(1) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1401)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01. The proposed rule would allow biosimilar products to be substituted for a prescribed biological product, in order to be consistent with federal law. There is no negative fiscal impact on the state general fund. Negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

(2) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy (Fee Rule) - Temporary and Proposed Rule (Docket No. 27-0101-1402)

The Board of Pharmacy submits notice of temporary and proposed rulemaking at IDAPA 27.01.01. The temporary and proposed rule defines outsourcing facilities, creates a new registration category for outsourcing facilities, establishes a registration fee, and establishes practice standards for outsourcing facilities. The purpose of the temporary and proposed rule is to make Idaho's regulatory scheme consistent with the federal Drug Quality and Security Act. There is no apparent negative fiscal impact on the state general fund. Negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

27-0101-1401

Intro:

Page #228 in your pending rules book.

270101-1401. Congress has created a new pathway for drug approval. These new drugs are collectively known as biosimilars and, by federal law and this pending rule, they must be highly similar to a specific reference biological product that is already an FDA approved drug. Biological products are large complicated molecules, as compared to most drugs which are generally easier to manufacture. Biological products are produced by living cells, and slight variations may exist from batch to batch within the brand name manufacturing process. As these molecules are so complicated and it's impossible to make an exact replica of a slightly moving target, generic drugs can not be made. Drugs work in the body by attaching to receptor sites, and only a small portion of the large biological product attaches to the receptor site. Generally speaking, creating an exact replica of a biological product is not necessary, if the part that adheres to the receptor site fits correctly. Not only do biological products have to be proven highly similar to a specific reference biological product in order to gain FDA approval, but they have to be proven safe and effective. Generic drugs do not have to prove that they are safe and effective, as their reference product's drug studies are utilized for generic FDA approval. The FDA approval for biosimilars is certainly a rigorous one, and I'm not aware of any opposition to it.

Federal law allows for a provision that goes beyond simply approving a biosimilar... by determining that the licensed biolsimilar is interchangeable with the referenced biological product. This docket of rules establishes the Idaho parameters for biosimilar interchange. Certain aspects of such interchangeability have become controversial.

Many states do not have to promulgate rules in order to substitute an FDA approved interchangeable biosimilar. Their rule language is more general, such as allowing substitution for "similar" drug products, which allows generic selection AND interchangeable substitution. Idaho's generic selection is specific to products listed in the FDA's Orange book. The FDA publishes all licensed biological products in the Purple Book. Therefore, rule promulgation is necessary in Idaho to allow substitution of FDA approved interchangeable biosimilars.

Efforts have been very successful in undermining the FDA biosimilar approval process, establishing fear that products that are only similar (and not exact) will potentially not work as well or cause potentially unwanted side effects. In reality, the FDA has established incredibly high standards for biosimilar interchangability including:

- biosimilars can be expected to produce the same clinical result as the reference product in any given patient; and
- the safety and reduced efficacy risks of alternating or switching are not greater than with repeated use of the reference product.

The FDA is traditionally a VERY conservative agency. The Board trusts that the FDA will not approve interchangability unless the products meet these extremely high standards.

The Board heard from patient advocacy groups and prescribing groups that utilize biological products at the Board's two public negotiated rule making sessions. The Board also heard over 50 pieces of public comment on the topic, more than the Board received when rewriting our entire set of rules...78 pages...in 2012. Negotiated rulemaking works! The Board altered much of their draft language and then altered much of their proposed language, pursuant to public comment,

to produce the pending rules before you. Much of the comment received was in support of the Board's proposal, but more of it was opposed. Again, the Board trusts the rigorous process that Congress and the FDA developed for the approval of biosimilars.

Many biosimilars have been available in the European market for decades, so these are often not unproven drugs. Biosimilars are typically expensive, injectable drugs. The Rand Corporation predicts that biosimilars will lead to a $44.2 billion dollar reduction in spending on biologic drugs in the United States over the next decade. Just last week an FDA panel unanimously approved the first biosimilar, and the FDA is expected to accept their report and license the first biosimilar in the United States later this year.

If this pending rule before you is defeated via concurrent resolution, biosimilar substitution will not be allowed in Idaho. We will be more restrictive than the federal government and we will not realize the full cost savings that biosimilars will provide. Thus, this promulgation is supported by groups like Blue Cross of Idaho, Regence Blue Shield of Idaho, Select Health, Pacific Source Health Plans, the National association of Chain Drug Stores, CVSHealth, Express Scripts, the Academy of Managed Care Pharmacy, the Pharmaceutical Care Management Association, The Idaho State Pharmacy Association, Idaho Retail PharmacyCouncil, and Mylan. The Board of Pharmacy does not often consider the financial aspect of the law. Our job is to protect public safety, not to save the state and its citizens money, but when healthcare costs prevent care from being administered at all, cost becomes a public safety issue.

Back to the language within the docket in front of you. After defining the various terms that I have used today, you will find pending changes to rule 130: drug product substitution. I don't often read changes word

for word, but for such a big topic, the language is short, so I will this time.

04. Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if:
a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; ( )

b. The prescriber does not indicate by any means that the prescribed biological product must be dispensed; and ( )

c. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. ( )

Opponents of this rule promulgation want to add, what the Board has determined to be an unneeded hindrance to FDA approved biosimilar interchangability: What is referred to as "notification" or "communication". These opponents will have you believe that without this provision a pharmacist will substitute an interchangeable biosimilar and the prescriber will not know what has been dispensed.

As previously mentioned, biologic drug therapy is very expensive. Third party payers, "insurance companies", and Medicaid typically do not pay for biologic drug therapy without a prior approval process. One physician testified at one of our negotiated rulemaking sessions that the prior approval process is often 6 weeks long. Certainly a physician is notified of the drug to be dispensed during the lengthy prior authorization process by the third party payer.

Also, the Idaho Health Information Exchange typically contains all data on dispensed drugs that are paid in full or in part by a third party payer. While the IHIE might not be as robust and used as often as all would like, the Board heard testimony that it typically contains 89% of all

dispensed prescriptions. The 11% that is missing are prescriptions that were paid for by cash, not typically expensive biologic drugs. Thus, there already is a common electronic system available to communicate what was dispensed, and it has 2,500 current users.

Biologics are not tablets that might get separated from the labeled vial they are dispensed in; these are injectable drugs, whereby every syringe is clearly labeled by the manufacturer with the identity of the product.

Proponents of a notification requirement will have you believe that communication is as easy as sending an e-mail, however this is also not true, as such an electronic transmission is often not HIPPA compliant.

Although the Board heard from Idaho patients and Idaho physicians, this is certainly a national effort. First, three states passed a bill requiring notification. Then, three states passed a bill requiring notification, but establishing a sunset, because they were not sure that notification should be required. Then, MA passed a law that defined notification as an accurate record in a pharmacy computer- not much of a notification requirement. Finally, FL passed a law without a notification provision, like the rule before you. Additionally, several of the state legislatures that I mentioned earlier, states that did not have to pass a rule to allow for biosimilar substitution, have rejected attempts to pass a bill that required notification. As this process unfolds, states are establishing that they don't legislate to potential fears and unfounded possibilities.

In conclusion, this pending docket of rules is the result of intense negotiated rulemaking. Most negotiated rulemaking results in compromise...meeting in the middle on an issue. The Board has done that. The changes due to public comment from the original draft that was distributed before the August 2014 negotiated rulemaking session

to the printing of proposed language were substantial. The changes due to public comment on the printed proposed language were substantial, creating the negotiated pending language before you. The Board's vote was unanimous. The Board firmly believes that this pending rule protects public safety and avoids implementing road blocks to saving the state of Idaho and its citizens health care dollars. The Board firmly believes that pharmacists should not have to participate in a duplicative act of communication that is not required by the Federal government.

The Board has received zero opposition to the language that is contained within the rule before you. This is a good rule. The opposition is to what the rule does not contain. It will most likely be years before an interchangeable biosimilar gains FDA approval. Thus, we have years to determine if notification should be required and what such a requirement might look like. With that I urge you to pass docket 27-0101-1401, and I will stand for questions.

NOT TODAY

Docket 27.0101.1402 starts on page 43 in your pending fee rule book. In late 2013, the federal compounding quality act created a new drug outlet type: the outsourcing facility. These facilities compound drug product and distribute the product to practitioner's for in office administration. As Idaho had no such registration category, a temporary rule was promulgated. Currently about 100 outsourcing facilities are federally registered at $15,000 per. None are located in Idaho, but they distribute into Idaho. Fees were established at the statutory maximum of $500 for initial registration and $250 for renewal. Registration application requirements include being federally registered, the identity of an Idaho registered or licensed pharmacist in charge, and a qualified inspection report. As most of outsourcing

27-0101-1401

Idaho Medical Association

July 28, 2014

Idaho Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
PO Box 83720
Boise, ID 83720-0067

Re: Comment on Idaho Board of Pharmacy
Rule Change Regarding Biologics and Biosimilars

The Idaho Medical Association is the preeminent statewide professional association representing approximately 2,000 Idaho physicians as well as several hundred physician assistants and nurse practitioners. We thank you for the opportunity for IMA to comment on the Board of Pharmacy's proposed rule on interchangeable biologic substitution. For our members who prescribe biologics the potential in the near future to have FDA approved, lower-cost interchangeable biosimilars available to patients is an exciting development.

It is our understanding that the FDA could approve the first biosimilar as soon as 2015. We also understand that the FDA can designate a biosimilar as "interchangeable" with an original biologic product. This is important given biologics are complex medicines made from living organisms with no two biologic medicines being exactly the same.

Because of these variations and the complexity of the conditions for which these medicines are prescribed, the IMA asks the Board of Pharmacy to incorporate the following points as you promulgate the rule on interchangeable biologic substitution:

Comment 1 – FDA Approved Interchangeable Biosimilars: We agree that the appropriate safeguard for substitution is FDA approved interchangeable biosimilars as defined in the proposed rule. As biosimilars are not exact copies, deferring to this higher level of review by the FDA is critical to ensuring physician confidence in permitting substitution of an available interchangeable biosimilar.

Comment 2 – Provide Biosimilars with the Same Safeguards as Generics: Again, it is important to note that biosimilars – even interchangeable biosimilars – are not exact copies like generic drugs. As such, the regulatory safeguards around interchangeable biosimilar substitution should be equal to, and ideally more than, the safeguards that are currently required for generic substitution. There are two important safeguards set forth

in generic substitution regulation with one allowing for prescriber autonomy and the other requiring record retention (see Idaho Administrative Code – Board of Pharmacy Section 131 – Drug Product Selection (01) and (02)). Neither of these safeguards is currently included in the proposed rule.

In order to ensure physician utilization and confidence in interchangeable biosimilars, physicians must have ultimate discretion over when a substitution can be made, as well as confidence there will be accurate documentation if a substitution occurs. If a physician believes that a brand is medically necessary then that brand shall be dispensed. Only if the physician does not specify a brand, can a biosimilar be dispensed by the pharmacist. The proposed rule should be amended to include these two important safeguards.

Comment 3 – Patient Counseling: The Board of Pharmacy already has provisions in both regulation and in statute that address patient counseling about the medicines they are taking. Under the proposed rule these patient protections would not apply to interchangeable biosimilars. The proposed rule needs to be amended to clarify that these requirements also apply to interchangeable biosimilars.

Comment 4 – Physician Communication: Due to the complexity of these products and the chronic nature of the patient population that are typically prescribed these products, it is imperative that the prescribing physician is made aware of the product dispensed once the substitution is made. There are many ways in which this information can be communicated to the physician or entered into the patient's medical record. Having this communication is a key component to any regulation governing interchangeable biosimilar substitution. This communication ensures an accurate patient record, but even more importantly, ensures we have informed patients and physicians which we know is critical to providing high quality, cost effective care.

Thank you once again for bringing this regulation forward as it is very timely. Let us know how the IMA can work more closely with you and the board as the regulation moves forward. We would appreciate the opportunity to discuss with you our comments and how best to get them incorporated into the final regulation.

Sincerely,

Susie Pouliot

Susie Pouliot
Chief Executive Officer

27-0101-1401

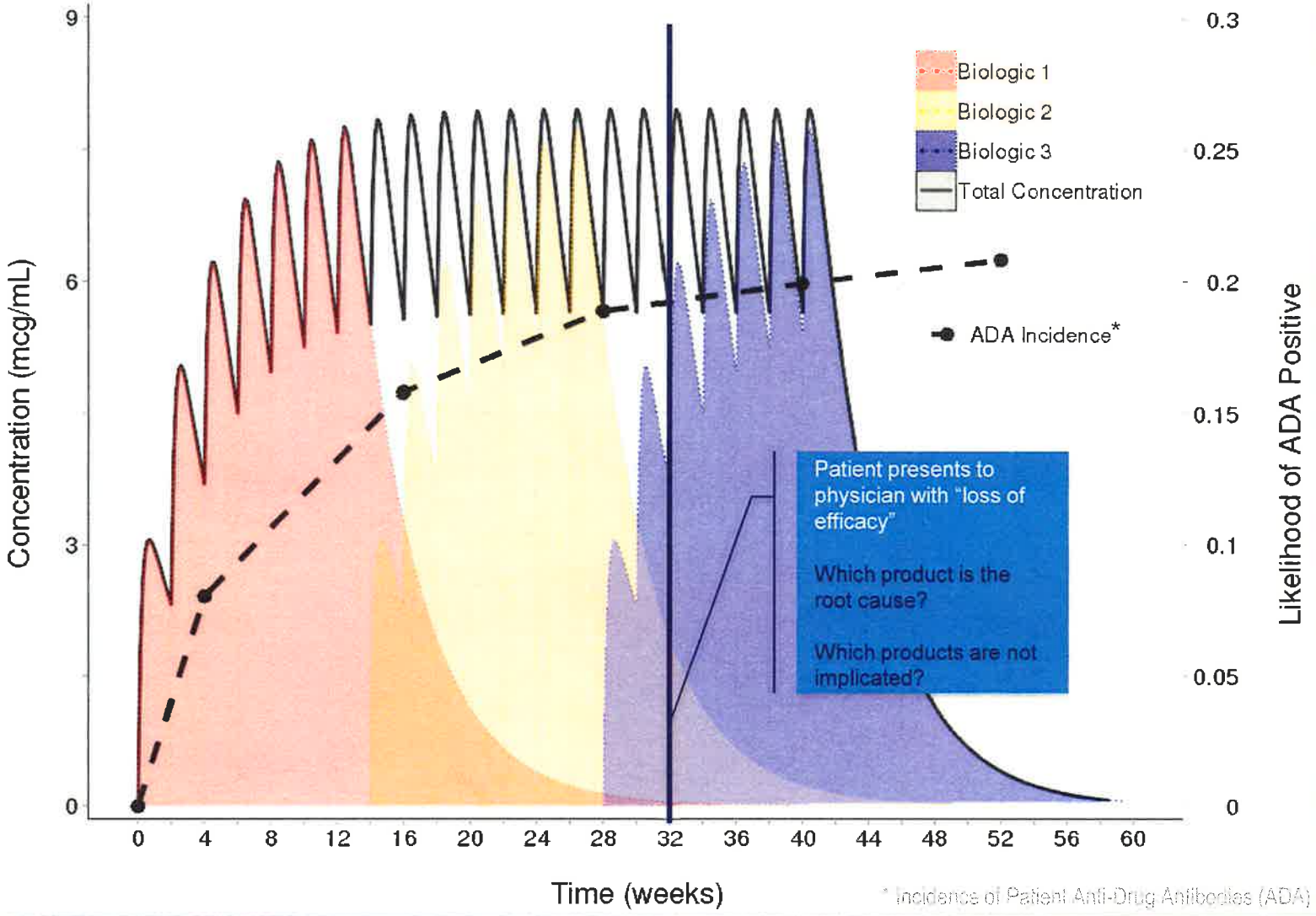
Generic Pharmaceutical Association

New Fall 2014 Compromise Language

Within a reasonable time following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry in an interoperable electronic medical records system or through an electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. If no such system is available between the pharmacist and prescriber, the pharmacist shall communicate the biologic product dispensed to the prescriber, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

- There is no FDA-approved interchangeable biologic for the product prescribed; or
- a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

Biologic adverse event attribution will be difficult without complete and accurate patient records



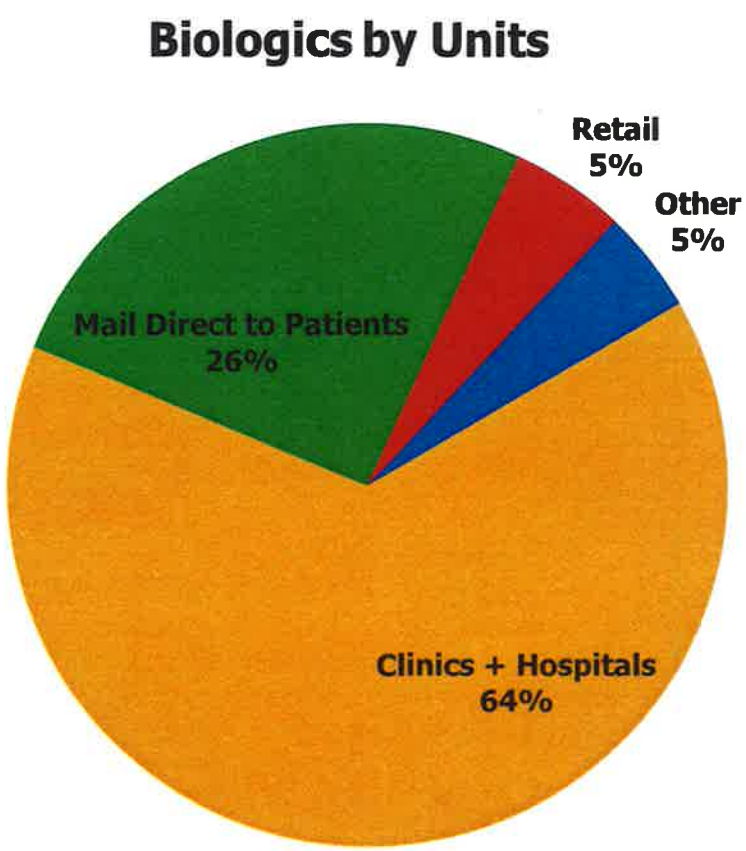
Simulation based on Bartelds, G., et al., Development of Antidrug Antibodies Against Adalimumab and Association With Disease Activity and Treatment Failure During Long-term Follow-up. Journal of the American Medical Association 2011: 305 (14): 1460-1468

Sources: Ben-Horin, S., et al., The decline of anti-drug antibody titres after discontinuation of anti-TNFs: implications for predicting re-induction outcome in IBD. Aliment Pharmacol Ther, 2012. 35(6): p. 714-22. and FDA Humira Clinical Pharmacology Review available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm080610.htm

AMGEN

2012 Distribution of Top* Biologics by Channel

* Top biologics are those constituting 1% or more of the total biologic sales. Chart represents 83.7% of total biologic sales volume by dollar



Definition of Channels

- "Hospitals & Clinics" include non-federal hospitals and clinics.
- "Mail Direct to Patients" includes product that flows through regular and specialty pharmacy mail service.
- "Retail" includes chain and independent pharmacies and food stores.
- "Other" includes federal facilities (e.g. veteran's medical facilities), HMOs, home health care, long term care, prisons, universities

Amgen analysis based on research using IMS data of 2012 National Sales Projections.
Units of molecules representing 1% or more of sales by dollar were included. Products included: ARANESP, AVASTIN, AVONEX, AVONEX PEN, BETASERON, ENBREL, EPOGEN, ERBITUX, HERCEPTIN, HUMIRA, LUCENTIS, NEULASTA, NEUPOGEN, ORENCIA, PEGASYS, PEGASYS CONVEN PACK, PEGASYS PROCLICK, PROCRIT, REBIF +, REMICADE, RITUXAN, STELARA, SYNAGIS, XGEVA, XOLAIR, YERVOY